PD5 Keller Opp Exh D - Purdue OMS Presentation

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Order Monitoring System (OMS):
A Manufacturer's Perspective

Presentation for HDMA Conference

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<u>Mission of the Purdue OMS Program</u>

To ensure compliance with DEA regulations requiring manufacturers and distributors to monitor and report suspicious orders of controlled substances, by implementing a detailed process for:

➢ **<u>Ongoing assessment of selected accounts</u>, including Purdue's authorized distributors and their retail customers**

➢ **<u>Support for authorized distributors</u> in implementing their OMS programs and efforts to "know their customers"**

➢ **<u>Reporting of suspicious ordering</u> to DEA, other law enforcement, or state licensing boards, as appropriate**

History of the Purdue OMS Program

➢ **Followed DEA correspondence to all registrants detailing obligations of manufacturers and distributors of controlled substances to:**

- **Conduct independent analysis and exercise due diligence to confirm legitimacy of orders and to scrutinize suspicious circumstances**
  - o Valid DEA registration not sufficient
  - o Know your customers and your customers' customers

- **Inform DEA of suspicious orders when discovered**

➢ **Expanded program launched in 2008**

➢ **SOP finalized in March 2009**

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OMS Program Team Members

OMS COMMITTEE CHAIRPERSON

VP & Associate General Counsel, Law Department

MEMBERS
VP, Corporate Security
Executive Director, DEA Compliance
Executive Director, National Accounts
Director, OMS Program Coordinator
Director/Investigations, Corporate Security

CONTRIBUTORS
VP, Health Policy
Attorney, Prescriber Program analysis
Professional Rep, Sales Force
Director, Sales Systems

OMS Information Sources

- ➢ **Fee For Service (FFS) Data**
    - **Order data for pharmacies + other dispensing outlets**
    - **Provided by authorized distributors under FFS Agreements**
    - **Loaded on monthly basis into OMS Database**
    - **Cover 97% of Purdue's product distribution**

- ➢ **IMS outlet/prescriber data & Sales Ops outlier analyses**

- ➢ **Sales Force reports of concern (ROC)**

- ➢ **Prescriber Program information**

- ➢ **Government agencies/law enforcement**
    - **DEA, local law enforcement, state licensing boards, legislative contacts**

- ➢ **Media reports**

<u>Prescriber versus Dispenser</u>

➢ **Prescriber program: Focus is on prescriber and Rx history /patterns**

➢ **OMS: Focus is on dispenser/pharmacist and ordering history/patterns**

➢ **Sharing of signal detection information between OMS and Prescriber programs**

- **Enables us to consider prescriber and pharmacy issues within particular geographic area**

- **Results in more robust information shared with internal (e.g., Risk Management) and external (e.g., authorized distributors) partners**

OMS Process

➢ **Identification of Potential Problematic Outlets ('09-'10)**

- **FFS Data Outliers – Outlets with orders outside normal range based on algorithm:**
  o Total volume of Purdue product orders
  o Percentage of OxyContin / non-OxyContin orders to total orders of Purdue products
  o Percentage of orders of higher dosages of OxyContin
  o Number of distributors from which outlet purchases
  o Number of orders of same product per day
  o Significant increases/changes comparing current 1, 3, 6 and 12 months to prior period

  Based on algorithm, **500-600 outlets met criteria**

OMS Process
(continued)

➢ **Identification of Problematic Outlets (continued)**

- **IMS Data Outliers**
  - o Outliers among retail outlets identified by Sales Ops' quarterly analysis of IMS Data

- **Outlets identified by other signals**
  - o Typically identified by sales force or authorized distributors
  - o Suspicious signals include:
    - ▪ Observed anomalies of pharmacy location, appearance/operation or clientele
    - ▪ Statements by pharmacy personnel indicating deficiencies in Rx verification or other abuse/diversion mitigation procedure**s**
    - ▪ Authorized distributor comparative data on other opioid dispensing by pharmacy or Rx detail on pharmacy's prescribers
    - ▪ Media reports of law enforcement or licensing board action

<u>OMS Process</u>
(continued)

➢ **Outlier Pharmacies Selected for Review:**

- **Top FFS Data Outliers (as ranked by Sales Ops)**
- **Accounts identified by authorized distributors**

➢ **Input from National Accounts**

- **Any prior knowledge of pharmacy, including factors that explain or heighten concern about outlier data**
- **Assessment of need for further follow up**

➢ **Input from Sales Force**

- **Review of prior ROCs**
- **Standard OMS follow with Rep / DM / RM**
- **Specific additional assistance occasionally requested**

<u>OMS Process</u>
(continued)

➢ **Review of Related Internal Data & Information**

- **Savings Card Pharmacy Redemption data**

- **Analysis of identified prescribers (IMS data)**

➢**Public Records Search**

- **Corporate security review of entity status and ownership, including related entities**

- **DEA registration / state licensing status and disciplinary actions**

- **Civil or criminal actions**

<u>OMS Process</u>
(continued)

➢ **DEA Compliance: Collaboration with Authorized Distributors**

- **Initial meetings to share information about respective order monitoring programs and procedures**

- **Ongoing information exchange and review of ordering data and other information pertaining to specific outlets**

- **Communication and collaboration on follow up with respect to individual outlets, which may include:**

  - o Outlet surveillance and/or site visit and interview of owner, Pharmacist-In-Charge and/or pharmacy staff
  - o Reduction or cut-off of supply to outlet
  - o Reporting to licensing board, DEA, other law enforcement

<u>Summary of OMS Meetings</u>

➢ **Order monitoring meetings held with authorized distributors plus ongoing contacts:**

- **Between Sept 2008 and March 2012, Purdue met in person with 10 separate wholesalers to discuss OMS programs and procedures, and opportunities for better collaboration**

- **Throughout that time, Purdue engaged in regular ongoing contact via conference calls and joint site visits to discuss particular accounts of concern and appropriate follow up**

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OMS Process
(continued)

➢ **OMS Report and Committee Decision**

- **Written report for OMS Committee review**
  - o Generated by Program Coordinator for each "outlier outlet"
  - o Captures information obtained during OMS review process

- **OMS Committee decision on each outlet reviewed**
  - o Pending: No decision pending completion of requested follow up
  - o Complete-closed: No suspicious ordering concern
  - o Complete-referred: Evidence of suspicious ordering and/or circumstances sufficient to refer to DEA, other law enforcement and/or state licensing board
  - o Continue to monitor: Suspicious circumstances warrant close monitoring, but not yet sufficient to refer

- **OMS Committee may recommend adjustments in shipments to distributor due to OMS concerns**

OMS Process: Post Reformulation

➢ **Updated Algorithm Based on Reformulation ('10 – '11)**

- **FFS Data Outliers – Outlets with decline in orders post OxyContin reformulation that met the following:**

  o Orders that met original algorithm

  o Significant declines/changes comparing current 3, 6 and 12 months of pre- versus post-reformulation data

  o Threshold 75% decline post reformulation

  o Percentage of OxyContin decline post reformulation vs contemporaneous increase in other opioids

  o Evaluate whether geographically located near prescribers of concern

  o Adjust threshold ($) to focus on significant accounts for review

  Based on new algorithm, **100 to 200 outlets met criteria**

<u>Meetings with DEA</u>

➢ **April 2009**
- Overview of OMS program
- Described collaboration with authorized distributors

➢ **April 2011**
- Overview of updated Purdue OMS program following reformulation
- DEA Registrant book shared
- Focus on prescriber data post-reformulation

➢ **October 2011**
- Focus on retail dispensing post-reformulation
- At request of DEA, provided calculation of all outlets with at least 50% decline and $350,000 in annual sales
- Total of 290 outlets identified (29 previously identified)

Summary of OMS Program Activity

(continued)

➢ Outlets Reviewed and/or Referred ('08 – '11)

- **Total: 365**

- **Breakdown by state:**
  - FL : 94
  - CA: 55
  - NY: 39
  - MI: 38
  - PA: 18
  - TN: 14
  - OH: 13
  - 27 States: 94 (3 to 4 each)

- **Breakdown by OMS Committee Action:**
  - Complete-Referred: 290
  - Complete-Closed: 75
  - Continue to Monitor: 8

Summary OMS Program Activity
(continued)

➢ **Outlets pending review/investigation**

- **Total:**   **8**

- **Breakdown by state:**
  - GA = 3
  - NY/NJ/CA/TN/IN = 5 (1 each)

➢ **Outlets subject to OMS Team Surveillance or Site Visits**

- **13 pharmacy site visits including interviews with owners or pharmacists in charge**
  - 6 of the visits conducted together with authorized distributors
  - Breakdown by location: 8 in Florida, 2 in California and Nevada, 1 in NY
- **10 additional pharmacies subject to surveillance**
  - 5 in California , 2 each in Ohio and Florida, 1 in Nevada
- **30 + site visits with wholesalers**

<u>OMS Program Challenges</u>

➢ **Data Gaps**

- **No data connecting outlets with individual prescribers**

- **No data from distributors with whom we have no FFS agreement**

- **FFS data excludes outlet-level order detail for:**
  - o Secondary distributors
  - o Dispensing outlets that opt out of data reporting

- **IMS data excludes prescribers/outlets who opt out of reporting**

- **Dispensing healthcare providers**

➢ **Not in doctors office, or at pharmacy, when prescriptions being written and filled**

➢ **Pressure Created by Geographic Hotspots (e.g., Florida, California, Tennessee, Georgia and Alabama)**

Recommendations: Lessons Learned

- ➤ **Quantities matter: excessive orders must be evaluated**

- ➤ **Meaningful scrutiny of dispensing: registration not sufficient**

- ➤ **Site visit due diligence: expected as part of follow up**

- ➤ **Cannot rely on third party: must do own due diligence**

- ➤ **Trend analysis is a key: compare similar products, size and location of outlets**

- ➤ **Threshold exceptions: must be individually reviewed and decisions properly documented**

- ➤ **Referrals to DEA: consider for all OMS actions regarding outlets**

Benefits of Collaboration: What can be gained?

➤ **Enhance collaborations efforts between wholesalers and manufacturers**

➤ **Greater information sharing: maximize resources (DEA, Wholesaler and Manufacturer)**

➤ **Achieve efficiencies with accounts identified for follow up**

➤ **Identify additional tools to address DEA's concerns (better data analysis, potential modeling)**

➤ **Mindful of anti-trust concerns**

Thank You

Any Questions